CLAIMS

1. Film-like, active substance-containing preparations for application in the oral cavity or for transmucosal application, characterized in that the preparation has a peroxide number of maximally 40.

2. Preparation according to claim 1, characterized in that it has a peroxide number which is maximally 15, preferably maximally 5.

3. Preparation according to claim 1 or 2, characterized in that it is substantially free of active oxygen, the term "active oxygen" referring to molecular oxygen as well as to oxygen-containing compounds wherein oxygen has an oxidation state higher than -2, especially peroxides with the general structure R-O-O-R', wherein R and R' are selected from the group consisting of alkyl residues and hydrogen, and wherein R and R' are the same or different.

4. Preparation according to any one of the above claims, characterized in that it contains at least one antioxidant, preferably selected from the group comprising ascorbic acid, ascorbylpalmitate, sodium sulfite, sodium disulfite, sodium metabisulfite, tocopherols (vitamin E), tocopherol acetate, thioglycerol, thioglycol acid, vitamin A, propyl gallate, octyl gallate, butylhydroxyanisol and butylhydroxytoluene.

5. Preparation according to claim 4, characterized in that the concentration of the antioxidant(s) is 0.001 to 5%-wt., preferably 0.01 to 3%-wt.

6. Preparation according to any one of the preceding claims, characterized in that it has a mono-layered or

multi-layered polymer matrix, with at least one layer having an active substance content.

7. Preparation according to claim 6, characterized in that the matrix contains one or more polymer(s) selected from the group comprising cellulose ether, especially ethyl cellulose, propyl cellulose, carboxymethyl cellulose (CMC), hydroxypropyl cellulose (HPC), hydroxypropylmethyl cellulose (HPMC), mixtures of cellulose ethers, as well as cellulose acetate, polyvinyl alcohols, polyvinyl acetate, polyvinyl pyrrolidone, polyethylene oxide polymers, polyurethane, polyacrylic acid, polyacrylates, polymethacrylates, alginates, pectins, gelatine, starch and natural rubbers.

8. Preparation according to claim 6, characterized in that the matrix contains one or more polymer(s) selected from the group of the hydrophile, water-soluble polymers or polymers degradable in aqueous media, preferably from the group comprising cellulose derivatives, especially hydroxypropylmethyl cellulose, carboxymethyl cellulose, hydroxypropyl cellulose and methyl cellulose, as well as polyvinyl alcohol, polyvinyl acetate, polyvinylpyrrolidone, polyacrylates, water-soluble polysaccharides, especially pullulan, xanthan, alginates, dextrane and pectins, proteins, preferably gel-forming proteins, especially gelatine.

9. Preparation according to any one of the preceding claims, characterized in that at least one layer or at least one surface of the preparation has mucoadhesive properties.

10. Preparation according to any one of the preceding claims, characterized in that it contains one or more additives selected from the group of plasticizers, dyes and

pigments, degradation enhancers, wetting agents, absorption- or permeation-enhancing substances, pH regulators, fillers, flavouring and aromatic substances and sweeteners.

11. Preparation according to any one of the preceding claims, characterized in that it contains at least one active substance which due to its chemical structure is susceptible to attack by peroxide radicals.

12. Use of a preparation according to any one of the preceding claims for transmucosal administration of medicinal active substances, preferably for application in the oral cavity.

13. Use of a preparation according to any one of the preceding claims as oral administration form for releasing active substances in the gastrointestinal tract.

14. Use of a preparation according to any one of the preceding claims for releasing flavouring or aromatic substances in the oral cavity.

15. Process for the production of a film-like active substance-containing preparation for application in the oral cavity or for transmucosal application, characterized by the following steps:

(a) Determining the peroxide number of each and every one of the formulation components provided for making the preparation according to recipe;

(b) selecting the formulation components in such a manner that the sum of the peroxide numbers of the individual formulation components is maximally 40, with the peroxide number of each one of the formulation components being weighted according to the percentage of these components in the preparation;

(c) preparing a solution, dispersion or melt which contains the selected formulation components as well as the active substance(s) to be released;

(d) coating this solution, dispersion or melt onto an inert support using doctor-knife application, roll application, spraying or extrusion methods, and subsequent drying or cooling, which results in the formation of a film layer.

16. Process according to claim 15, characterized in that the sum of the peroxide number is maximally 15, preferably maximally 5.

17. Process according to claim 15 or 16, characterized in that, following step (a), at least one formulation component is subjected to a treatment with reducing agent(s) which is/are suitable for reducing the peroxide content.

18. Process according to claim 17, characterized in that the mentioned treatment is carried through in such a manner that the aqueous solution of an inorganic sulfite salt or hydrogen sulfite salt, preferably sodium sulfite or sodium hydrogen sulfite, is added to the formulation component in an alcoholic solution, preferably in methanolic or ethanolic solution.